U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210

OCT 2 0 1999

Kenneth Olden, Ph.D.
Director
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

Dear Dr. Olden:

Thank you for your letter of February 16, 1999, regarding the position of the Occupational Safety and Health Administration (OSHA) on the use of the Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals/Compounds. At issue is the acceptability of the Murine Local Lymph Node Assay under OSHA's Hazard Communication standard [(HCS); 29 CFR 1910.1200].

The HCS requires manufacturers and importers to perform a hazard determination for the product(s) they manufacture or import to determine if, under the normal condition of use or in an emergency, workplace handling or use of their product(s) can or could result in employee exposure to a hazardous chemical(s). OSHA does not perform these hazard determinations for manufacturers; rather, it is up to the manufacturers and importers to consider all available scientific evidence concerning the hazardous effects of that chemical. **No testing is required and the evaluation may be based solely on the information currently available in the scientific literature.**

The use of short term tests (i.e., *in vitro* studies) has not been specifically addressed in either the text of the HCS final rule (59 FR 6126) or the preamble discussions. However, Appendix B states:

> The results of **any** studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and [be] reported on any material safety data sheet (MSDS).

It is the manufacturer's responsibility to review all available scientific data when performing a hazard determination for the chemicals they produce. If the *in vitro* studies, conducted according to established scientific principles, report statistically significant conclusions regarding the health effects of a chemical, and if these are the only data available linking the hazard to the chemical exposure, these studies **must** be reported on the product's MSDS. It must be emphasized that the

Agency does not encourage replacing *in vivo* tests with *in vitro* studies. In general, the Agency's policy on *in vitro* tests is that "*in vitro* studies... are useful pieces of information, but not definitive finding of hazards" (CPL 2-2.38D, Appendix C).

OSHA has actively participated in the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and in the process for the validation of this test method. OSHA believes that the independent review and validation process of the ICCVAM makes these determinations scientifically sound as required by Appendix B. Therefore, based on ICCVAM's independent review and validation of this method, the Agency will accept any positive study conducted using the Murine Local Lymph Node Assay as a means of assessing the allergic contact dermatitis potential of a chemical. However, it must be made clear that although the Agency will accept any positive results from the Murine Local Lymph Node Assay as an indicator of allergic contact dermatitis potential for the chemical, negative results would not be considered to rule out the possibility of this hazard.

The Agency will inform the regulated community of this decision by publishing a Federal Register notice in the near future. Also, the Agency will inform the field by providing compliance officers with copies of this letter, the Federal Register notice, and the ICCVAM Report.

I hope that we have provided you with enough information to state the Agency's position on the Murine Local Lymph Node Assay. If you require additional information, please feel to contact us.

Sincerely,

Charles N. Jeffress
Assistant Secretary